



Long-term outcome of laparoscopic ventral rectopexy for full-thickness rectal prolapse: the PEXITY study

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Abstract

Background Laparoscopic ventral mesh rectopexy (LVR) has gained increasing acceptance for the treatment of patients with a full-thickness rectal prolapse (RP), but literature on follow-up of at least 10 years is scarce. We studied recurrence rate, long-term functional results and quality of life in patients who had LVR for RP more than 12 years ago.

Method The study population consisted of patients who could be contacted among the 175 who had undergone LVR for RP and whose short- and medium-term outcomes were published in 2012. We studied the long-term recurrence rate (Kaplan-Meier), functional outcome (Wexner and ODS scores), quality of life (EuroQoL) and satisfaction of the patient through clinical examination(s), specific scores and questionnaires.

Results Of the 175 patients, 14 patients had exclusion criteria, 57 had died, and 42 were lost to follow-up, leaving 62 patients for analysis. Seventeen patients presented with a recurrence (10.5%) at the 10-year follow-up. The only statistically significant risk factor for recurrence was recurrent RP (HR = 11.5 (2.54–52.2), $P = 0.002$). The median faecal incontinence score was 4 (0–10) and significantly worse in patients who had a recurrence [12 (7–13) vs 3 (0–9); $P = 0.016$]. The median obstructive defaecation score was 6 (3–12). The median quality of life score was 7 (6–8). Most patients who presented with a recurrence said they would undergo the operation again and recommended it, as would patients with no recurrence.

Conclusion LVR for RP is a safe and efficient technique with sustainable long-term results that shows long-term efficacy at > 10 years after the operation.

Keywords Full-thickness rectal prolapse · prolapse recurrence · laparoscopic ventral rectopexy · long-term functional results · quality of life

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Introduction

Laparoscopic ventral mesh rectopexy (LVR), as described by D'Hoore et al., has gained increasing acceptance for the treatment of patients with a full-thickness rectal prolapse (RP) [1, 2]. The operation corrects the anatomical anomaly and strengthens the rectovaginal septum. Dissection is limited to the anterior aspect of the lower rectum followed by a mesh suspension to the sacral promontory. Avoidance of extensive rectal mobilization minimizes the risk of pelvic nerve damage and related constipation [1, 3]. We conducted a review of the literature on LVR for RP and concluded that, based on the published favourable outcome data in terms of a low complication rate, low de novo constipation rate, improvement of anal incontinence and low recurrence rate at mid and long term, LVR seems to emerge as an efficient procedure for the treatment of patients with RP [4].

Nevertheless, some recent questions about ventral rectopexy for RP are still debated, such as the interest in a robotic approach [5–9], using a biological mesh [10], the using glue [11] or staplers [12] for mesh fixation, the advantage of an associated sigmoid resection [13, 14], the alternative of suture rectopexy [15–17], or perineal stapled prolapse resection [18].

In this context and to serve as a reference against which future studies can be compared, we aimed to study the recurrence rate, long-term functional results, quality of life and satisfaction in patients who had undergone LVR for RP (but not for rectocele, enterocele or internal prolapse) > 10 years ago in a single large university hospital.

Methods

Patients and study design

Between May 1996 and June 2009, 206 patients were operated on for RP in our colorectal unit. Of these patients, 175 (17 male) of mean age 58 (range, 16–94) years had a LVR; 17 patients were operated on using the ViKY Robotic Scope Holder (Endocontrol Medical, Grenoble, France) as part of a prospective randomized study [5]; 3 patients were operated on with the Da Vinci robot (Intuitive Surgical, Inc., Sunnyvale, CA, USA) at the beginning of our experience in robotic surgery [6, 8].

For the 175 patients, RP had been present for on average 29 months (range, 2–744); one woman aged 62 had had RP since infancy. Fifteen patients were referred with a recurrence. RP was diagnosed in the standing, squatting and lateral decubitus position at rest and during straining. Dynamic video cysto-colpo-proctography in women or video proctography in men were performed in all patients before the operation to confirm exteriorized rectal prolapse and reveal any eventual associated pelvic floor disorder. The radiological technique has been described elsewhere [19]. During the same period, and essentially from 1996 to 2002, 14 other patients underwent ventral rectopexy by laparotomy and 17 underwent a perineal procedure under locoregional or local anaesthesia for RP. Reasons for an open or perineal approach are detailed in Supplementary material 1.

The short- and long-term technical results, with a mean follow-up of 74 (range, 24–181) months in the 175 patients with RP who underwent LVR, were published in 2012 [20]: there was no 30-day mortality and 5.1% severe morbidity grade IIIb in the Dindo-Clavien classification [21], and two patients presented with a recurrence of RP at month 6 and 24, giving a recurrence rate of 3% at 5 years [20].

This population served as a base for the present retrospective, single-centre study. The patients were contacted by phone from June 2020 onwards (i.e., > 10 years after the

operation on the last patient). Those who responded were given verbal and written information about the study and if they agreed were asked to sign informed consent and complete a set of questionnaires. They were offered a consultation with a colorectal surgeon participating in the study. In the absence of a reply after many attempts, their family and general practitioner were contacted, before declaring death or loss to follow-up.

Exclusion criteria were patients who refused to participate, those deprived of liberty by judicial or administrative decision, under legal protection, or patients with missing data essential for the study.

Patients' characteristics extracted from the prospectively maintained institutional database for the 2012 study included age, sex, body mass index (BMI), American Society of Anaesthesiologists (ASA) score, past history of hysterectomy, previous surgery for RP whatever the technique and approach, psychiatric disease including past anorexia nervosa, history of chronic constipation and/or obstructive defaecation syndrome (ODS) [22], faecal incontinence defined as a Jorge and Wexner score > 5 [23], onset of the prolapse defined as < 1 year, ≥ 1 but < 5 years and ≥ 5 years, conversion to laparotomy, and associated cystopexy and/or colpopexy and/or other procedure.

Surgical technique

The procedure was derived from the original open technique described by Loygue et al. in 1984 [24], modified by D'Hoore et al. [1] and extensively described as laparoscopic anterior rectopexy to the promontor [20]. Laparoscopy or a robotic approach was performed through four trocars, as shown on two recently published videos [25, 26] (Fig. S1). The procedure is extensively described in Supplementary material 2, and an operative view of the mesh fixation is shown in Fig. S2.

Endpoints and long-term assessments

The primary endpoint for this analysis was the recurrence rate calculated according to the Kaplan-Meier method. Recurrence was defined as the presence of RP on physical examination. Date of recurrence, date of surgical treatment if any, type of surgery and outcome were collected. Risk factors for recurrence were also studied.

Secondary endpoints were the long-term functional outcome, quality of life and satisfaction of the patient collected during the interview and clinical examination for those who had responded. Faecal incontinence was given by the Jorge and Wexner score. Transit constipation was studied through two questions: Are you constipated? What treatment do you use to treat constipation? ODS was studied through the validated ODS score [27]. Quality of life was studied using

the validated EuroQoL scale EQ-5D-3L [28]. To be able to interpret this quality of life, we assessed the general health status of the patients with a visual analog scale (VAS) from 0 (the worst state of health imaginable) to 100 (the best). Patient satisfaction regarding the operation was collected using a VAS from -5 (very disappointed) to $+5$ (very satisfied) and through two questions: If you had to have the procedure again, would you do it (yes, perhaps, certainly not)? Would you recommend this rectopexy operation to family or friends?

Institutional review board (IRB) approval

The trial protocol was approved by the French Ethics Committee CPP Sud Méditerranée IV on October 2, 2020 (IRB no. 2020-A02293-36) and the French Health Authority (ANSM) was informed. The study was registered in the CHU Grenoble Alpes register of studies respecting the reference methodology MR003 of the National Commission for Informatics and Liberties (CNIL).

Statistical analysis

Categorical variables are presented as numbers and percentages. Continuous variables are presented as the median and

25th–75th percentiles. A recurrence-free curve was generated using the Kaplan-Meier method. For patients who had died or were lost to follow-up, data were censored at the time of death or last documented follow-up.

Both univariate and multivariate analyses were conducted to identify factors associated with recurrence. A Cox model was employed to estimate hazard ratios and their confidence intervals. The multivariate analysis was adjusted for clinically significant variables, including age, sex, BMI, ASA score, history of hysterectomy, psychiatric disorders, chronic constipation and late onset of prolapse. P value < 0.05 was considered statistically significant. Statistical analyses were performed using R version 4.3.3.

Results

Of the 175 patients who were treated by LVR for RP in our institution until June 2009 and selected, 14 patients had exclusion criteria. From the 161 eligible patients, 57 had died including 34 before 10 years of follow-up, and 42 were lost to follow-up, leaving 62 patients who signed the inform consent and responded to the questionnaires (Fig. 1). Characteristics of the 161 eligible patients are presented in Table 1.

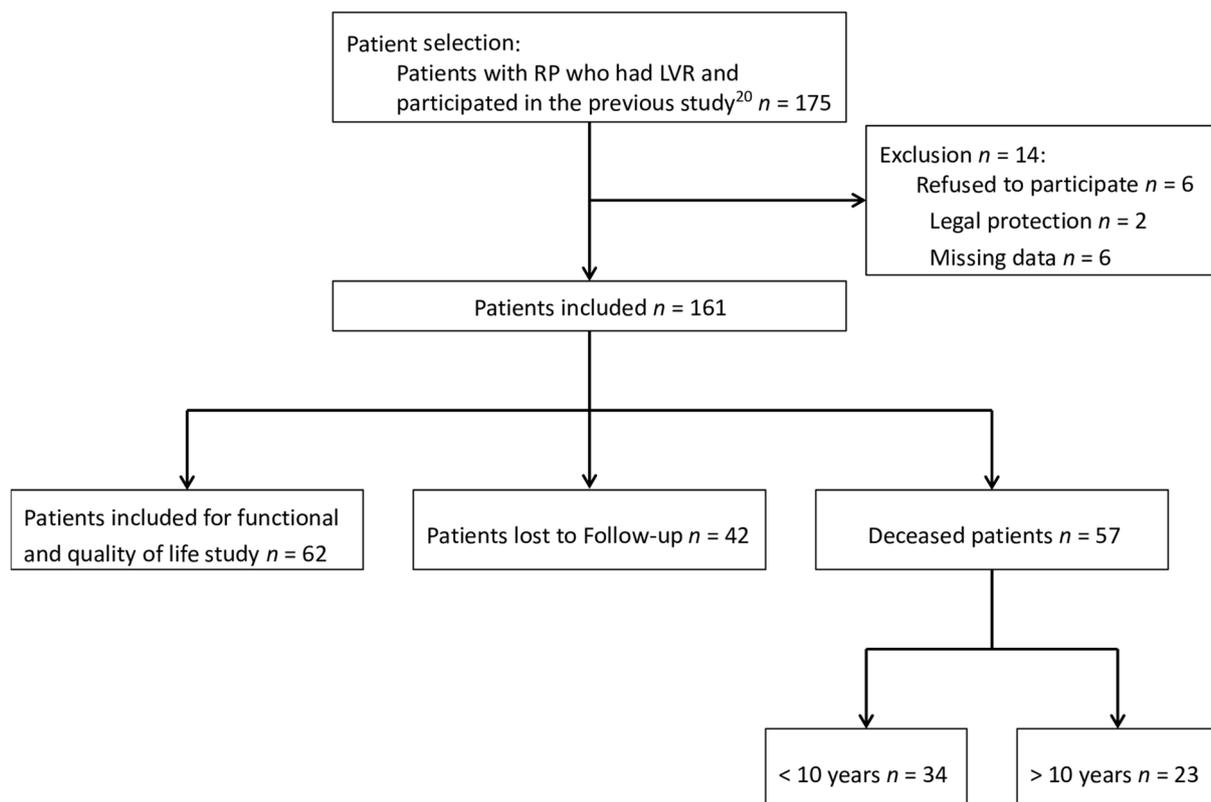


Fig. 1 Flow diagram of participant selection

Table 1 Baseline characteristics of study population

	All patients <i>n</i> = 161	Patients with no recurrence <i>n</i> = 144	Patients with recurrence <i>n</i> = 17
Age (years), median (i.q.r., range)	58 (46–73, 16–94)	60 (46–74, 16–94)	51 (48–66, 18–80)
Female sex	147 (91%)	132 (92%)	15 (88%)
BMI (kg/m ²), median (i.q.r., range)	22.9 (19.2–25.3, 14.6–36.7)	22.9 (19.7–25.3, 14.6–36.7)	22.3 (17.1–31.6, 17.1–31.6)
ASA score > 2	14 (8%)	11 (9.2%)	3 (18%)
Past history of hysterectomy	53 (36%)	50 (37.8%)	3 (20%)
Recurrent rectal prolapse*	15 (9.3%)	9 (6.3%)	6 (35.2%)
Psychiatric disorders	12 (7.4%)	11 (7.6%)	1 (5.9%)
Constipation and/or ODS	140 (86.9%)	129 (89.5%)	11 (64.7%)
Anal incontinence	101 (62.7%)	87 (60.4%)	14 (82.3%)
Onset of rectal prolapse [§]			
< 1 year	41 (33%)	35 (31%)	6 (43%)
≥ 1 but < 5 years	49 (39%)	45 (40%)	4 (29%)
≥ 5 years	36 (29%)	32 (29%)	4 (29%)
Conversion to open procedure	2 (1.2%)	2	0
Associated procedure	24 (14.2%)		
Cystopexy	2	2	0
Abdominal wall repair	6	5	1
Colpopexy	4	4	0
Other gynaecologic [†]	7	7	0
Miscellaneous [‡]	5	3	2

Values are *n* (%) unless otherwise indicated. BMI, body mass index; ASA, American Society of Anaesthesiology; ODS, obstructive defaecation syndrome

*Seven patients had had a laparoscopic (4) or open (3) rectopexy, five a Delorme procedure and three an Altemeier procedure

[§]Missing data: 35

[†]Ovarian kystectomy in three, myomectomy in two, subtotal hysterectomy in one, and tubar ligation in one

[‡]Right colectomy for a caecal villous tumour in one, haemorrhoidectomy in one, ascites drainage in one, left colostomy in one and rectopexy mesh removal in one

From the total cohort of 161 patients, 17 presented with a recurrent RP at 10-year follow-up, with a median (i.q.r.) interval time of 78 (10–120) months, giving a raw recurrence rate of 10.5%. Of these 17 patients, 8 had undergone redo ventral rectopexy (Fig. 2), 4 the Altemeier procedure and 3 the Delorme procedure, all with uneventful technical recovery except for one redo ventral rectopexy in a woman whose laparoscopy had been converted because of a presacral vein haemorrhage and reoperated at day 6 for adhesiolysis. The last two patients were not reoperated because of their short prolapse size with few symptoms and refusal of further surgery. The baseline characteristics of the patients with and without a recurrence are shown in Table 1.

Univariate analysis showed that recurrent RP [HR = 6.48 (2.37–17.7); *P* = 0.001] was a confounding factor for repeat recurrence. In multivariate analysis, the only statistically significant risk factor for recurrence was recurrent RP [HR = 11.5 (2.54–52.2); *P* = 0.002] (Table 2). In other words, redo rectopexy has higher risk for recurrence than primary operation. Age, sex, BMI, ASA score, history of hysterectomy, psychiatric disorders, chronic constipation

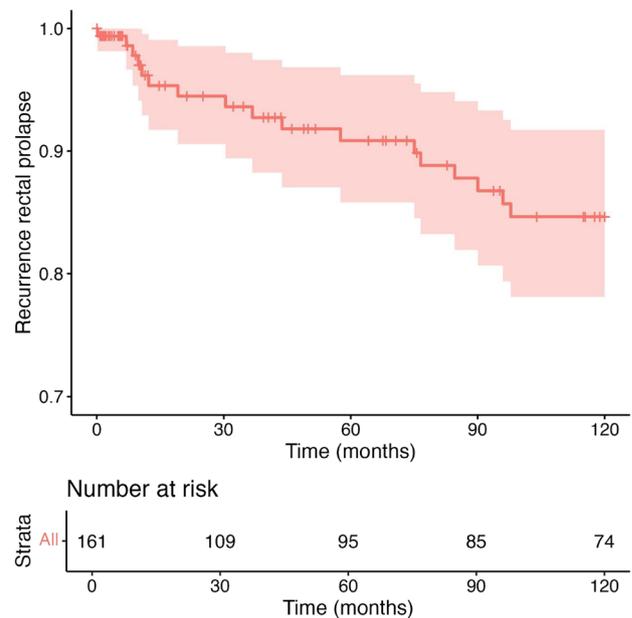


Fig. 2 Kaplan-Meier analysis estimating the probability of recurrence over time

Table 2 Univariate and multivariate logistic regression analysis of risk factors for recurrence

	Univariate analysis		Multivariate analysis	
	HR	P	HR	P
Age (years)	0.98 (0.96, 1.01)	0.200	0.98 (0.95, 1.01)	0.200
Sex				
Female	–		–	
Male	3.18 (0.72, 14.1)	0.130	4.02 (0.58, 27.7)	0.200
ASA score				
< 3	–		–	
≥ 3	2.37 (0.68, 8.33)	0.200	2.81 (0.54, 14.7)	0.200
History of hysterectomy	0.38 (0.11, 1.33)	0.130	0.85 (0.15, 4.71)	0.900
Recurrent rectal prolapse	6.48 (2.37, 17.7)	0.001	11.5 (2.54, 52.2)	0.002
Psychiatric disorders	0.89 (0.12, 6.69)	0.900	0.80 (0.09, 7.07)	0.800
Constipation and/or ODS	0.63 (0.23, 1.71)	0.400	1.11 (0.28, 4.40)	0.900
Onset of rectal prolapse				
< 1 year	–		–	
≥ 1 but < 5 years	0.54 (0.15, 1.91)	0.300	0.42 (0.09, 1.85)	0.200
≥ 5 years	0.67 (0.19, 2.39)	0.500	0.85 (0.18, 4.01)	0.800

Values in parentheses are 95% confidence intervals

HR hazard ratio, ASA American Society of Anaesthesiologists, ODS obstructive defaecation syndrome

and late onset of prolapse were not associated with risk of recurrence in this study. Excluding the 15 patients who were initially referred to us with recurrent RP gives a recurrence rate of 7.5%, which reflects the true recurrence rate for patients operated on for primary RP in our institution using the anterior rectopexy technique.

Functional results, quality of life and patient satisfaction for the 62 patients who responded to the questionnaires are shown in Table 3. The median (i.q.r.) Jorge and Wexner score was 4 (0–10) and significantly worse in patients who had a recurrence ($P=0.016$). Median (i.q.r.) ODS score was 6 (3–12) with a tendency towards a worse score in the patients who had a recurrence. All patients without recurrence reported an improvement in their anorectal function. The median (i.q.r., min-max) quality of life score given by the EuroQol scale was 7 (6–8) and similar in both groups; general health status established at a median (i.q.r.) level of 70 (50–80) on the VAS was similar in both groups.

Despite more severe anal incontinence scores, a tendency towards difficulty in rectal evacuation and dissatisfaction, most patients who presented with a recurrence would undergo the operation again and recommend it to friends and family, as would patients with no recurrence (Table 3).

Discussion

The actuarial 10-year recurrence rate of 10.5% in this study, and 7.5% when patients referred for a recurrent RP were excluded from the analysis, is within the lower range of the published recurrence rates of the main series of abdominal

rectopexy with follow-ups of at least 10 years [15, 29, 30]. In a multicentre pooled analysis of 643 individual patients including 320 patients with mesh rectopexy, published in 2005, data showed a 10-year recurrence rate of 28.9% [29]. In 2014, Foppa et al. reported a raw 10-year recurrence rate of 18% in 179 patients after laparoscopic suture rectopexy [15]. The 10-year RP recurrence rate following LVR in the study by Consten et al. was 8.2% (13 patients) [30], but eight patients developed symptomatic “internal rectal prolapse with or without enterocele” recurrence requiring surgical correction that we did not observe in our series, leaving a “true” recurrence rate for rectal prolapse requiring surgery of nearly 13% in this study.

The wide range of variation in recurrence rates after abdominal surgery for RP has several explanations that have been explored by DiGiuro et al. [31] and more recently discussed by van der Schans et al. [32]. The variation in recurrence rate first reflects differences in the length of follow-up between studies, with lower RP recurrence rates at shorter follow-up [4]. Articles reporting on LVR for RP describe time intervals to recurrence of between 6 and 90 months after surgery. The present study falls within this range with a median time to recurrence of 78 months. Recurrence developing within the first 36 months usually reflects technical failure, but not all studies report on this time interval [30]. Raftopoulos et al. showed that the 5-year recurrence rate after surgery can quadruple at 10 years [29]. In our series, the 5-year recurrence rate tripled beyond 10 years from 3 to 10.5%. Therefore, we agree with Consten et al. who insisted on the need to have long-term follow-up data to evaluate the ultimate efficacy of rectopexy [30]. A second important

Table 3 Functional results, quality of life and satisfaction of study population who responded to the questionnaire

	All patients <i>n</i> = 62	Patients with no recurrence <i>n</i> = 54	Patients with recurrence <i>n</i> = 8	<i>P</i> value ¹
Wexner score, median (i.q.r.)	4 (0–10)	3 (0–9)	12 (7–13)	0.016
Missing data	0	0	0	
Patients with Wexner score > 5	27	18	9	
ODS score, median (i.q.r.)	6 (3–12)	6 (2–11)	11 (7–14)	0.076
Missing data	3	2	1	
EuroQol scale, median (i.q.r., range)	7 (6–8, 0–13)	7 (6–8, 0–13)	7 (6–7, 5–8)	0.800
Missing data	0	0	0	
General health status, median (i.q.r.)	70 (50–80)	70 (50–80)	68 (55–76)	0.700
Missing data	1	1	0	
Satisfaction score, median (i.q.r., range)	5 (3–5, – 5 to 5)	5 (4–5, – 5 to 5)	1 (– 3 to 3, – 5 to 5)	0.004
Missing data	3	2	1	
Would you have the operation again?				0.600
Yes	46 (81%)	41 (80%)	5 (83%)	
No	1 (1.8%)	1 (2%)	0 (0%)	
Perhaps	10 (18%)	9 (18%)	1 (17%)	
Missing data	5	3	2	
Would you recommend it to family or friends?	50 (91%)	45 (92%)	5 (83%)	0.500
Missing data	7	5	2	

Values are *n* (%) unless otherwise indicated

ODS obstructive defaecation syndrome

¹Fisher's exact test; Wilcoxon rank sum test

factor influencing the recurrence rate is the initial indication for surgery. Some cohorts included only external prolapse patients, others only internal rectal prolapse patients, or only enterocele/rectocele patients, or mixed series. While external prolapse is a clear diagnosis made on physical examination or defecography, internal rectal prolapse and colpocele diagnoses are less straightforward [31]. Radiological images of intussusception or rectocele at the end of rectal evacuation without complaint can even be considered normal [33]. The various definitions of recurrence could explain variations in recurrence rates among cohorts. The third cause suggested in the literature could be the nature of the mesh. Mackenzie et al. found that the only predictor of recurrence was the use of polyester mesh, which generated a significant twofold increase in recurrence rate, compared with the use of a polypropylene graft [34]. However, an analysis of 643 patients suggested that the surgical technique, such as the method of rectopexy and access, does not affect the recurrence rate [29]. It therefore seems appropriate to look further for other biases that could explain the variations in recurrence rate in the literature. An important factor is the heterogeneity amongst cohorts regarding the percentage of patients who had undergone previous surgery for RP (ranging from 0 to 41%) [32]. Perrenot et al. showed that patients with previous pelvic floor surgery or surgery for a recurrent RP had more recurrences of RP (21.0% versus 10.7%) [35]. We observed

the same tendency, and for us this was the only risk factor for recurrence. Another factor relates to heterogeneity in the learning curve. Our retrospective series involved learning curves for LVR and for robotic surgery of RP; indeed, our current long-term recurrence rate is lower than that reported here. Some authors have argued the need for extensive rectal mobilization to minimize RP recurrence [36]. However, we observed recurrence rates even lower than for rectopexy techniques that require more extensive rectal mobilization [37–39]. Lastly, while some recurrences occur because of dehiscence of the mesh from the sacral promontory or the rectum, other factors can also contribute to failure of rectopexy, such as persistence of the cause responsible for or favouring the RP in the first place, for example, severe transit constipation, the practice of certain sports or professions, or specific conditions such as Ehlers Danlos disease, Marfan disease, or use of corticosteroids.

While the recurrence rate is the key measure of a successful outcome, patient reported endpoints are also important, including function and quality of life [36]. Surgical repair for RP also aims to improve anorectal function. We observed low median values for the Wexner and ODS scores. These findings correlate with the literature on LVR without posterior rectal mobilization, showing a mean decrease of 45% in faecal incontinence and a mean decrease of 40% in constipation [37]. We observed no new-onset constipation in our

study. Consten et al. only noted new-onset constipation in 22 (2.4%) patients [30]. A systematic review on functional outcomes of different rectopexy techniques reported new-onset constipation in 5.5% to 10.5% cases for LVR without posterior rectal mobilization [37]. Mäkelä-Kaikkonen et al. studied the long-term functional results in a multicentre cohort of 330 patients operated on for external or internal rectal prolapse with a median follow-up of 44 months and demonstrated that subjective symptom relief was experienced by 86% of patients with external rectal prolapse [40]. In a recent systematic review and meta-analysis, Emile et al. found that the weighted mean rates of improvement in faecal incontinence and constipation after LVR were 79.3% and 71%, respectively [41]. We found in our study that patients with recurrent RP had a worse functional result than those without recurrence. Nevertheless, the patients with recurrence were overall satisfied with their care and presented similar quality of life scores. Singh et al. analysed the patients' perception of their long-term outcome after LVR for various indications and reported that overall 63% of patients were satisfied with the outcome and 76% would recommend this procedure to others with similar symptoms [42]. For RP, we also found that the majority of patients having had a LVR in our institution would undergo the operation again and would recommend it to family and friends, even in the case of recurrence.

The principal limitation of this study is its retrospective character; nevertheless, very few events like complications and recurrence were missed by the analysis. Although the Kaplan-Meier method yields appropriate estimates for recurrence at various points in time, underestimation remains possible. A second limitation is the very long follow-up of the study, with the first patients having been operated on > 25 years ago. Many patients died or were lost to follow-up by the time of the analysis in 2020 and later, and this could have introduced a bias. The third major limitation is the absence of baseline functional evaluations of anal incontinence, constipation, obstructed defaecation and baseline quality of life. Some validated scores or questionnaires were not available at the beginning of the study period. These limitations should be considered in the interpretation of the long-term outcome and underline the necessity for the better functional and global evaluation of benign disorders such as RP.

Conclusion

LVR for RP is a safe and efficient technique with sustainable long-term results that shows long-term efficacy at > 10 years after the operation.

Supplementary Information The online version contains supplementary material available at <https://doi.org/10.1007/s10151-024-03104-0>.

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Author contributions J.L.F. participated in the study design. J.L.F., J.F., F.T., B.T. participated in the methodology. F.T., B.T., P.Y.S., D.D., J.L.F. participated in the data collection. M.B., G.M., A.R., J.L.F., P.Y.S., B.T. participated in the data analysis/interpretation. M.B., J.L.F., A.F., B.T. participated in the writing. M.B., G.M., A.R., F.T., P.Y.S., B.T., J.L.F. participated in the critical revision/final approval.

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Data availability The data collected and analysed in this study are available for academic use on reasonable request to the corresponding author and will be the object of a data release contract signed by the applicant and Grenoble Alpes University Hospital.

Declarations

Conflict of interest None of the authors has a conflict of interest concerning this work.

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